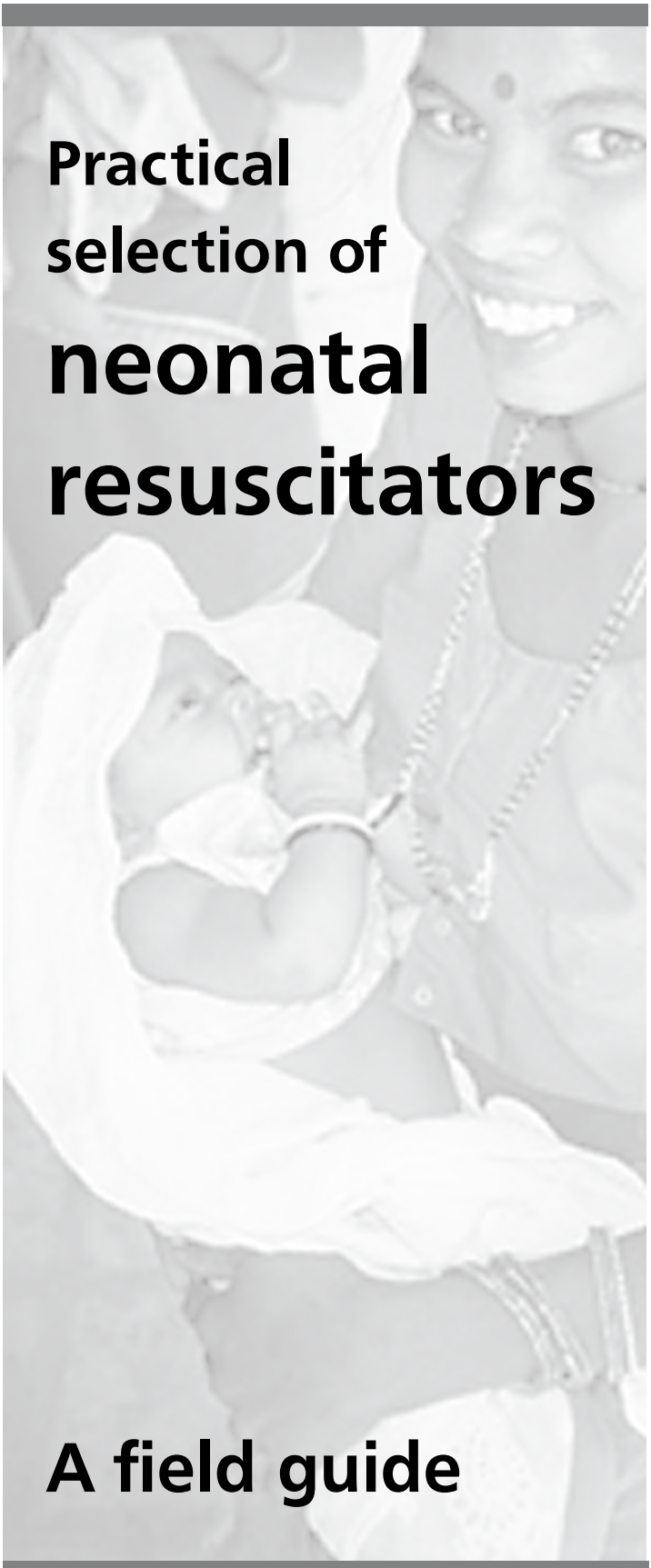
Practical selection of neonatal resuscitators



A field guide

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Neonatal Resuscitators

Neonatal resuscitators are critical components in any program developed to lower the rate of neonatal mortality due to birth asphyxia. However, with the wide variety of resuscitators available on the global market, choosing a resuscitator best suited to your program may be a difficult and confusing process.

PATH conducted an evaluation of a cross section of neonatal resuscitators that included disposable and reusable bag and mask and tube and mask models.

This pamphlet provides some of the results of this evaluation and includes:

- Background on neonatal resuscitation.
- PATH's suggestions for choosing a resuscitator.
- Information about the evaluation criteria.
- Comparison of 11 currently available resuscitators based on PATH's evaluation.

Importance of Resuscitation

Birth asphyxia refers to the condition when a baby does not breathe at birth. Asphyxia is estimated to account for one-third of the estimated four million neonatal deaths that occur annually. This results in over one million neonatal deaths and an unknown number of infants with long-term neurological disability. Reducing birth asphyxia and neonatal death requires appropriate care including a resuscitator available at every birth.

Neonatal resuscitators, when properly used, can lower the incidence of mortality associated with neonatal asphyxia. In order to achieve this, resuscitators need to be made available to all birth attendants in conjunction with adequate training.

Mechanics of Resuscitation*

Newborn resuscitation should begin as soon as asphyxia is identified. After clearing the airway and correctly positioning the newborn's head and neck, the health worker positions the mask over the mouth and nose and holds it with light pressure to form an airtight seal. Breaths should then be delivered at a rate of 40–60 breaths per minute. While it may be uncommon to have an in-line manometer (pressure gauge), caregivers should observe the infant's chest to ensure chest rise with each breath. Typical pressures may exceed 30 cm H_2O for the initial breath and then typically diminish to 15–20 cm H_2O. Tidal volumes are small, typically 5–8 ml/kg of newborn weight.

How to Choose a Resuscitator

☑ Choose desired features.

Features on most resuscitator models are similar, but variation exists. Depending on your program, features such as oxygen ports and reservoirs, high-quality packaging, or a compact profile may be important.

☑ Choose bag and mask or tube and mask.

Both types of resuscitators can reduce the incidence of neonatal mortality but each has distinct advantages and disadvantages.

☑ Decide between disposable and reusable.

Depending on the nature of your program and the rate of neonatal asphyxia, single-use or multiuse resuscitators may be more cost-effective. If the environment of use indicates that resuscitators will always be reused, it may be advisable to invest in a multiuse resuscitator to permit correct cleaning and disinfection after use.

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* This section provides a brief overview of a resuscitation procedure but is not meant to be a substitute for proper instruction. More information can be found from the Neonatal Resuscitation Program–online at http://www.aap.org/nrp/nrpmain.html and from the International Guidelines for Neonatal Resuscitation http://pediatrics.aappublications.org/cgi/content/full/106/3/e29 [accessed July 5, 2005].

☑ Decide on a price range.

Resuscitators are now available from a wide variety of manufacturers and can vary widely in price despite having many of the same features. Resuscitators manufactured in the United States or Europe are often higher priced than similar resuscitators manufactured in other countries.

Single-Use vs. Multiuse Resuscitators

Single-use (disposable) resuscitators can be lower priced than similar reusable models. However, single use resuscitators are often manufactured with lower cost materials that cannot be reprocessed and are often sealed to prevent disassembly.

Multiuse (reusable) resuscitators are often higher priced than similar disposable models. Reusable resuscitators are typically designed for both disassembly and reprocessing (including autoclaving). Due to the possibility of reuse, the cost per use of multiuse resuscitators may be lower than similar single-use resuscitators.

Important Features for Safe and Proper Resuscitation

Properly Sized and Form-Fitting Mask

Proper resuscitation depends on a good seal between the resuscitator and the neonate. Resuscitators are equipped with a variety of mask types including air-filled anatomically shaped masks or round, one- or two-piece masks (with a silicone flange). Resuscitators generally include one mask size, and purchasers may want to purchase an additional mask for each resuscitator (to cover both low-birthweight and full-term neonates).

Pressure Relief Valve (bag and mask only)

Preventing lung damage is a paramount concern for anyone performing resuscitations. A pressure relief valve is designed to limit the pressure that the resuscitator can deliver. All bag and mask resuscitator

models tested had a relief valve except the Blue Cross resuscitator. No tube and mask resuscitators tested had a relief valve. *Note: Many of the models evaluated lacked any indication regarding the position of the valve—enabling the user to disable the relief valve without knowledge.*

Minimal Dead Airspace

Resuscitators that minimize dead airspace between the neonate's face and the nonrebreathing valve prevent the neonate from rebreathing expelled air with a higher concentration of CO_2. *Note: Dead airspace volume was not determined during this evaluation.*

Designed for Assembly/Disassembly

Ridged surfaces on parts that disassemble help identify these parts to the user as well as make the resuscitator easier to disassemble with wet hands. Color coding can help users distinguish different components, and quality design can augment the ease of assembly and disassembly.

Critical decision

Bag and Mask

Pros

- Pressure-limiting valve on many models reduces risk of lung rupture.
- More familiarity on part of providers.
- Wider variety on the market.

Cons

- Higher cost.
- More parts.

Properly Sized Bag (bag and mask only)

A bag specifically designed for providing appropriate tidal volumes for neonates can help reduce errors during use and simplify training. Most bag and mask models had bags that evaluators felt were appropriately sized except the Laerdal The Bag™ (shown at right).

Standard Mask Connections

Standard-sized connections are important to ensure compatibility with replacement components and masks from other manufacturers. Standard connections are a 15 mm inner diameter and a 22 mm outer diameter mask connector. Similarly, masks stems should have a 15 mm outer diameter or 22 mm inner diameter.

Which is right for your program?

Tube and Mask

Pros

- Often lower cost than bag and mask devices.
- Users may feel greater control delivering the pressure and monitoring the neonate's progress.
- Fewer parts.

Cons

- Fatiguing to use.
- Users may need additional training and practice to provide proper and consistent resuscitation.
- Caregiver cannot give instructions or counseling during resuscitation.

Guide to the Device Comparison Tables (pp. 10–20)

For each of the devices, the following information is provided in order to assist the reader in making an informed choice when purchasing a neonatal resuscitator. More information about specific resuscitators may also be available from the individual manufacturer or distributor.

The ASTM standard used as the basis for several evaluations is F920-93 Standard Specifications for Minimum Performance and Safety Requirements for Resuscitators Intended for Use with Humans.

Device Information

This section provides basic information on model number, supplier, website to get more information electronically, and price (as of December 2004).

Features That Count

This section provides information on features that have been identified as particularly important in resuscitator selection.

- **Mask size:** Size of mask(s) included with resuscitator.
- **Mask type:** Type of mask included with resuscitator.
- **Properly sized bag:** Based on user input and international guidelines.
- **Pressure relief valve/position indication:** Inclusion of a pressure relief valve. Clear indication if valve was engaged or disengaged. More information on proper valve operation can be found in the Resuscitator Parameters section (see pg. 7).
- **Designed for assembly/disassembly:** Whether the resuscitator was designed to facilitate assembly and disassembly.
- **Standard mask connections:** Whether the resuscitator has standard mask connections that

will permit it to be used with masks from other manufacturers or differently sized masks (e.g., neonate, low birth weight).

Device Features

This section provides information on:

- **Components:** Extra components included with the resuscitator.
- **Features:** Additional features of the resuscitator that are not required for basic operation.
- **Packaging:** Description of resuscitator packaging.
- **Single-use/multiuse:** Whether the resuscitator is designated by the manufacturer for single or multiple uses.
- **Size and weight:** Overall maximum dimensions and weight.

Resuscitator Parameters

This section provides information from laboratory testing on:

- **Pressure-limiting valve:** The pressure recorded at the patient connection port when air at a flow rate of 15 L/min was passed through the resuscitator (per ASTM standards). This test evaluates the proper function of the pressure-limiting valve in relation to the manufacturer's designation.
- **Pressure-limiting valve (during simulated use):** The maximum pressure recorded at the patient connection port when the resuscitator was connected to an artificial lung and the resuscitator was operated with rapid compressions.
- **Maximum tidal volume:** The maximum tidal volume achieved by the resuscitator attached to a test lung when a user fully squeezed the bag using all four fingers. In some cases, two volumes are recorded if tidal volumes were higher if the pressure relief valve was overridden.

Laboratory Evaluations

This section provides information from laboratory testing on:

- **Cleaning–effectiveness:** Evaluated by introducing simulated vomit into the device via the facemask, allowing the resuscitator to dry for one hour, and cleaning the resuscitator in a detergent solution using a soft-bristled brush. Score is based on the amount of simulated vomit remaining on the device after one minute of cleaning.
- **Disinfection–device durability:** Disassembled resuscitators were submerged in a 0.5% chlorine solution for 24 hours and evaluated for damage. No microbiological evaluation was conducted to determine the degree of disinfection.
- **Instructions–completeness:** Instructions included with the resuscitators were evaluated for completeness based on complete and correct information, accompanying diagrams, technical information, and reuse instructions.
- **Instructions–ease of reading:** Instructions were evaluated using a Flesch Reading Ease score, a method based on the length of words and sentences. Flesch scores are assigned a grade level as follows: Very difficult–post graduate; Difficult–College; Fairly difficult–High School; Standard–8th to 9th grade; Fairly easy–7th grade; Easy–5th to 6th grade; Very easy–4th to 5th grade.

User Feedback

This section provides information gathered from user feedback during evaluations conducted with 10 skilled and 23 unskilled users:

- **Ease of use:** Describes the ability of the user to intuitively adopt correct and consistent use of the resuscitator.
- **Perceived comfort:** Indicates the perceived comfort during use of the resuscitator.
- **Disassembly/reassembly:** Describes the ease and completeness of disassembly and reassembly by users without written instructions.

Usability

This section provides information from evaluations conducted with 10 skilled and 23 unskilled users. Researchers observed and recorded information on the following factors:

- **Appropriate rate:** As measured during a two-minute simulated resuscitation using a test lung. In this case, appropriate resuscitation rate is defined as between 40 and 60 breaths per minute, and the rating reflects the ability of users to maintain this rate.
- **Use consistency:** Indicates the number and significance of problems observed or noted during use.
- **Device ergonomics:** Describes an ergonomic analysis of the resuscitators as performed by the evaluation team. This includes size of device in relation to hand size, features to improve comfort or usability, and interaction of users with the device.

Evaluations Performed but not Included in Comparison Table

Several additional tests were performed during the evaluation but were not included in the comparison table. All bag and mask resuscitators were found to meet the ASTM standards for inspiratory and expiratory resistance and were able to provide greater than 200 compressions per minute. All resuscitators were able to be rinsed clean in less than 30 seconds after simulated contamination, operate properly after immersion in water, and operate after exposure to elevated temperatures. Exposure to low temperatures was found to temporarily affect the operation of bag and mask devices designed for single use. If users plan to store or use their resuscitators at cold temperatures (<0°C), a silicone bag may be more appropriate.

Blue Cross

Device Information	Model Number	IBW-01
	Supplier	Blue Cross Emergency Co. 3-12-9, Hongo, Bunkyo-ku Tokyo 131-0033, JAPAN 81-03-3815-2220
	Website	www.bluecross-e.co.jp/
	Cost (as purchased)	US$95.99
Features That Count	Mask size	Full-term neonate
	Mask type	Round two-piece. Clear hard plastic top; opaque silicone face seal
	Properly sized bag	Yes
	Pressure relief valve/position indication	No/N/A
	Designed for assembly/ disassembly	Yes
	Standard mask connections	Yes
Device Features	Components	Open-end oxygen reservoir
	Features	
	Packaging	Plastic resealable bag inside cardboard box
	Single-use/Multiuse	Multiuse
	Size (LxW) and weight	26 cm x 14 cm; 243 g
Resuscitator Parameters	Pressure-limiting valve (@ 15 L/min air flow)	N/A
	Pressure-limiting valve (during simulated use)	120 cm H_2O
	Maximum tidal volume	182 ml
Laboratory Evaluations	Cleaning—effectiveness	❸
	Disinfection—device durability	❸
	Instructions—completeness	❷ (indicates that 50 cm H_2O pressure should be generated)
	Instructions—ease of reading	Standard
User Feedback	Ease of use	❸
	Perceived comfort	❷
	Dissassembly/reassembly	❸
Usability	Appropriate rate	❹
	Use consistency	❹
	Device ergonomics	❸

❶ Very good ❷ Good ❸ OK ❹ Fair ❺ Poor

CPR-Pro Rescuer

Device Information	Model Number	#4000IN Rescuer Infant
	Supplier	CPR-Pro.com Inc 518 Fourth Line Oakville, Ontario L6L 5A7 CANADA 905-827-6320
	Website	www.cpr-pro.com
	Cost (as purchased)	US$12.99
Features That Count	Mask size	Full-term neonate
	Mask type	Anatomical air-filled
	Properly sized bag	Yes
	Pressure relief valve/position indication	Yes/No
	Designed for assembly/ disassembly	No (designed for single use)
	Standard mask connections	Yes
Device Features	Components	Oxygen reservoir bag; oxygen tubing connector
	Features	Pressure-limiting valve
	Packaging	Plastic drawstring bag inside cardboard box
	Single-use/Multiuse	Single-use
	Size (LxW) and weight	23 cm x 13 cm; 161 g
Resuscitator Parameters	Pressure-limiting valve (@ 15 L/min air flow)	38 cm H_2O
	Pressure-limiting valve (during simulated use)	54 cm H_2O
	Maximum tidal volume	185 ml (203 ml without pressure relief valve)
Laboratory Evaluations	Cleaning—effectiveness	❸ (no disassembly)
	Disinfection—device durability	❶ (no disassembly)
	Instructions—completeness	❸ (brief without illustrations)
	Instructions—ease of reading	Difficult
User Feedback	Ease of use	❷
	Perceived comfort	❷
	Dissassembly/reassembly	N/A
Usability	Appropriate rate	❸
	Use consistency	❶
	Device ergonomics	❷

❶ Very good ❷ Good ❸ OK ❹ Fair ❺ Poor

Hospitak/ Unomedical

Device Information	Model Number	1054-E (Neonate mask)
	Supplier	Tri-Anim 13170 Telfar Ave Sylmar, CA 91342 UNITED STATES 800-874-2646
	Website	www.tri-anim.com
	Cost (as purchased)	US$8.15
Features That Count	Mask size	Full-term neonate
	Mask type	Anatomical air-filled with refillable bladder
	Properly sized bag	N/A
	Pressure relief valve/position indication	No
	Designed for assembly/ disassembly	No (designed for single use)
	Standard mask connections	Yes
Device Features	Components	No additional components
	Features	N/A
	Packaging	Disposable plastic bag
	Single-use/Multiuse	Single-use
	Size (LxW) and weight	30 cm x 7.5 cm; 77 g
Resuscitator Parameters	Pressure-limiting valve (@ 15 L/min air flow)	N/A
	Pressure-limiting valve (during simulated use)	N/A
	Maximum tidal volume	N/A
Laboratory Evaluations	Cleaning—effectiveness	❷
	Disinfection—device durability	Filter becomes wet
	Instructions—completeness	No instructions included
	Instructions—ease of reading	N/A
User Feedback	Ease of use	❸
	Perceived comfort	❸
	Dissassembly/reassembly	Limited disassembly
Usability	Appropriate rate	❹
	Use consistency	❸
	Device ergonomics	❷

❶ Very good ❷ Good ❸ OK ❹ Fair ❺ Poor

Laerdal The Bag

Device Information	Model Number	84002903
	Supplier	Laerdal 167 Myers Corners Rd Wappingers Falls, NY 12590-8840 UNITED STATES 800-431-1055
	Website	www.laerdal.com
	Cost (as purchased)	US$139.50 (for 10 devices–US$13.95 per device)
Features That Count	Mask size	Full-term neonate
	Mask type	Anatomical air-filled with refillable bladder
	Properly sized bag	Yes (largest bag in review)
	Pressure relief valve/position indication	Yes/Cannot disable
	Designed for assembly/disassembly	No (designed for single use)
	Standard mask connections	Yes
Device Features	Components	Oxygen reservoir bag; oxygen tubing connector
	Features	Pressure-limiting valve
	Packaging	Disposable plastic bag
	Single-use/Multiuse	Single-use
	Size (LxW) and weight	29 cm x 12.5 cm; 230 g
Resuscitator Parameters	Pressure-limiting valve (@ 15 L/min air flow)	Not tested due to technical difficulties
	Pressure-limiting valve (during simulated use)	46 cm H_2O
	Maximum tidal volume	188 ml (708 ml without pressure relief valve)
Laboratory Evaluations	Cleaning—effectiveness	❸
	Disinfection—device durability	❷
	Instructions—completeness	❷ (no reuse information)
	Instructions—ease of reading	Difficult
User Feedback	Ease of use	❷
	Perceived comfort	❷
	Dissassembly/reassembly	N/A
Usability	Appropriate rate	❹
	Use consistency	❷
	Device ergonomics	❸

❶ Very good ❷ Good ❸ OK ❹ Fair ❺ Poor

Laerdal Silicone

Device Information	Model Number	860056
	Supplier	Laerdal 167 Myers Corners Rd Wappingers Falls, NY 12590-8840 UNITED STATES 800-431-1055
	Website	www.laerdal.com
	Cost (as purchased)	US$195.00
Features That Count	Mask size	Full-term neonate (0/1)
	Mask type	Round one-piece silicone
	Properly sized bag	Yes
	Pressure relief valve/position indication	Yes/Cannot disable
	Designed for assembly/ disassembly	Yes
	Standard mask connections	Yes
Device Features	Components	Oxygen reservoir bag
	Features	Pressure-limiting valve
	Packaging	Plastic resealable bag inside cardboard box
	Single-use/Multiuse	Multiuse
	Size (LxW) and weight	30.5 cm x 14.5 cm; 250 g
Resuscitator Parameters	Pressure-limiting valve (@ 15 L/min air flow)	32 cm H_2O
	Pressure-limiting valve (during simulated use)	40 cm H_2O
	Maximum tidal volume	125 ml (304 ml without pressure relief valve)
Laboratory Evaluations	Cleaning—effectiveness	❸
	Disinfection—device durability	❶
	Instructions—completeness	❶
	Instructions—ease of reading	Difficult
User Feedback	Ease of use	❸
	Perceived comfort	❷
	Dissassembly/reassembly	❸
Usability	Appropriate rate	❸
	Use consistency	❷
	Device ergonomics	❸

❶ Very good ❷ Good ❸ OK ❹ Fair ❺ Poor

P.J. Dahlhausen

Device Information	Model Number	CH436-51.5000.00.100
	Supplier	P.J. Dahlhausen & Co. Emil-Hoffmann-Str. 53 50996 Koln GERMANY 49-2236-39-130
	Website	www.dahlhausen.de
	Cost (as purchased)	US$122.55
Features That Count	Mask size	Full-term and low-birthweight neonate included
	Mask type	Round one-piece silicone
	Properly sized bag	Yes
	Pressure relief valve/position indication	Yes/Cannot disable
	Designed for assembly/ disassembly	Yes
	Standard mask connections	Yes
Device Features	Components	None included
	Features	Pressure-limiting valve
	Packaging	Disposable bag inside cardboard box
	Single-use/Multiuse	Multiuse
	Size (LxW) and weight	25 cm x 14 cm; 211 g
Resuscitator Parameters	Pressure-limiting valve (@ 15 L/min air flow)	23 cm H_2O
	Pressure-limiting valve (during simulated use)	42 cm H_2O
	Maximum tidal volume	61 ml (135 ml without pressure relief valve)
Laboratory Evaluations	Cleaning—effectiveness	❷
	Disinfection—device durability	❶
	Instructions—completeness	❶ (in English and German)
	Instructions—ease of reading	Fairly difficult
User Feedback	Ease of use	❸
	Perceived comfort	❸
	Dissassembly/reassembly	❸
Usability	Appropriate rate	❸
	Use consistency	❹
	Device ergonomics	❷

❶ Very good ❷ Good ❸ OK ❹ Fair ❺ Poor

Portex 1st Response

Device Information	Model Number	8527MPB
	Supplier	Smiths Medical 10 Bowman Drive Keene, NH 03431 UNITED STATES 603-352-3812
	Website	www.smiths-medical.com
	Cost (as purchased)	US$26.66
Features That Count	Mask size	Neonate and infant
	Mask type	Anatomical air-filled; fixed bladder
	Properly sized bag	Yes
	Pressure relief valve/position indication	Yes/Not adjustable
	Designed for assembly/ disassembly	No (designed for single use)
	Standard mask connections	Yes
Device Features	Components	PEEP valve; oxygen reservoir bag; oxygen tubing connector
	Features	Pressure-limiting valve; orifice covers
	Packaging	Plastic resealable bag with instructions printed on bag
	Single-use/Multiuse	Single-use
	Size (LxW) and weight	25 cm x 12 cm; 161 g
Resuscitator Parameters	Pressure-limiting valve (@ 15 L/min air flow)	36 cm H_2O
	Pressure-limiting valve (during simulated use)	49 cm H_2O
	Maximum tidal volume	105 ml
Laboratory Evaluations	Cleaning—effectiveness	❷
	Disinfection—device durability	❷
	Instructions—completeness	❷ (no reuse information)
	Instructions—ease of reading	Fairly difficult
User Feedback	Ease of use	❷
	Perceived comfort	❷
	Dissassembly/reassembly	N/A
Usability	Appropriate rate	❸
	Use consistency	❶
	Device ergonomics	❷

❶ Very good ❷ Good ❸ OK ❹ Fair ❺ Poor

Rescuer Silicone BVM Resuscitator

Device Information	Model Number	#4525
	Supplier	BLS Systems Limited 1108 South Service Road West Oakville, Ontario L6L 5T7 CANADA 905-339-1069
	Website	www.blssystemsltd.com
	Cost (as purchased)	US$45.00
Features That Count	Mask size	Low-birthweight neonate (0)
	Mask type	Round one-piece silicone
	Properly sized bag	Yes
	Pressure relief valve/position indication	Yes/No
	Designed for assembly/ disassembly	Yes
	Standard mask connections	Yes
Device Features	Components	Oxygen reservoir bag; oxygen tubing connector
	Features	Pressure-limiting valve
	Packaging	Plastic drawstring bag
	Single-use/Multiuse	Multiuse
	Size (LxW) and weight	23 cm x 12 cm; 176 g
Resuscitator Parameters	Pressure-limiting valve (@ 15 L/min air flow)	36 cm H_2O
	Pressure-limiting valve (during simulated use)	46 cm H_2O
	Maximum tidal volume	153 ml
Laboratory Evaluations	Cleaning—effectiveness	❶
	Disinfection—device durability	❶
	Instructions—completeness	❷ (not specific for infant resuscitation)
	Instructions—ease of reading	Difficult
User Feedback	Ease of use	❷
	Perceived comfort	❷
	Dissassembly/reassembly	❷
Usability	Appropriate rate	❸
	Use consistency	❷
	Device ergonomics	❷

❶ Very good ❷ Good ❸ OK ❹ Fair ❺ Poor

Silicone Infant Resuscitator

Device Information	Model Number	
	Supplier	Kay and Company 25, Netaji Subhash Marg New Delhi – 110 002 INDIA 91-11-51562801-05
	Website	www.kaycoindia.com
	Cost (as purchased)	US$21.00
Features That Count	Mask size	Low-birthweight neonate (0)
	Mask type	Round one-piece silicone
	Properly sized bag	Yes
	Pressure relief valve/position indication	Yes/No
	Designed for assembly/ disassembly	Yes
	Standard mask connections	Yes
Device Features	Components	Oxygen reservoir bag; oxygen tubing connector
	Features	Pressure-limiting valve
	Packaging	Nylon bag with drawstring inside cardboard box; instructions printed on bag
	Single-use/Multiuse	Multiuse
	Size (LxW) and weight	23 cm x 11 cm; 175 g
Resuscitator Parameters	Pressure-limiting valve (@ 15 L/min air flow)	50 cm H_2O
	Pressure-limiting valve (during simulated use)	46 cm H_2O
	Maximum tidal volume	109 ml (122 ml without pressure relief valve)
Laboratory Evaluations	Cleaning—effectiveness	❶
	Disinfection—device durability	❶
	Instructions—completeness	❺ (brief and incomplete)
	Instructions—ease of reading	Easy
User Feedback	Ease of use	❷
	Perceived comfort	❷
	Dissassembly/reassembly	❸
Usability	Appropriate rate	❸
	Use consistency	❷
	Device ergonomics	❷

❶ Very good ❷ Good ❸ OK ❹ Fair ❺ Poor

Tekno

Device Information	Model Number	N/A
	Supplier	F2H (Frontiers For Health) Jl. Cilaki 35 Bandung 40114 INDONESIA 62-22-7273125 Contact: Mrs. Atte Triyanti (Product Division)
	Website	N/A
	Cost (as purchased)	US$9
Features That Count	Mask size	Full-term neonate
	Mask type	Round two-piece mask with silicone face piece
	Properly sized bag	N/A
	Pressure relief valve/position indication	No
	Designed for assembly/ disassembly	Yes
	Standard mask connections	Yes
Device Features	Components	No additional components
	Features	N/A
	Packaging	Sealable plastic bag
	Single-use/Multiuse	Multiuse
	Size (LxW) and weight	29 cm x 6 cm; 59 g
Resuscitator Parameters	Pressure-limiting valve (@ 15 L/min air flow)	N/A
	Pressure-limiting valve (during simulated use)	N/A
	Maximum tidal volume	N/A
Laboratory Evaluations	Cleaning—effectiveness	❶
	Disinfection—device durability	❶
	Instructions—completeness	Instructions in Indonesian; line drawings; training information
	Instructions—ease of reading	Not evaluated due to language
User Feedback	Ease of use	❸
	Perceived comfort	❸
	Dissassembly/reassembly	❷
Usability	Appropriate rate	❹
	Use consistency	❸
	Device ergonomics	❸

❶ Very good ❷ Good ❸ OK ❹ Fair ❺ Poor

Topster

Device Information	Model Number	SR-003
	Supplier	Sturdy Industrial Co., Ltd. PO Box 2-023 Sanchung Taiwan REPUBLIC OF CHINA 886-2-89769455
	Website	www.sturdy.com.tw
	Cost (as purchased)	US$47.00
Features That Count	Mask size	Low-birthweight neonate
	Mask type	Round one-piece silicone
	Properly sized bag	Yes
	Pressure relief valve/position indication	Yes/Yes (if markings are comprehended)
	Designed for assembly/ disassembly	Yes
	Standard mask connections	Yes
Device Features	Components	Oxygen reservoir bag; oxygen tubing connector; 40-, 50-, 60-mm airways
	Features	Pressure-limiting valve
	Packaging	Plastic hard case with handle
	Single-use/Multiuse	Multiuse
	Size (LxW) and weight	24.5 cm x 11 cm; 188 g
Resuscitator Parameters	Pressure-limiting valve (@ 15 L/min air flow)	42 cm H_2O
	Pressure-limiting valve (during simulated use)	63 cm H_2O
	Maximum tidal volume	94 ml (132 without pressure relief valve)
Laboratory Evaluations	Cleaning—effectiveness	❷
	Disinfection—device durability	❶
	Instructions—completeness	❷
	Instructions—ease of reading	Fairly difficult
User Feedback	Ease of use	❷
	Perceived comfort	❷
	Dissassembly/reassembly	❸
Usability	Appropriate rate	❷
	Use consistency	❷
	Device ergonomics	❷

❶ Very good ❷ Good ❸ OK ❹ Fair ❺ Poor

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